A randomised controlled trial to compare the clinical efficacy and acceptability of adjustable intermittent and continuous Negative Pressure Wound Therapy (NPWT) in a new portable NPWT system*

Martin Forlee,1 Louis van Zyl,2 Hein Louw,3 Jeanne Nel,4 Nyda Fourie,5 Robert Hartley6

All trademarks acknowledged. ™Trademark of Smith & Nephew. 14373 | GMC0615 Poster presented at the European Wound Management Association annual meeting, May 9-11, 2018, Krakow, Poland

Introduction

• Animal studies show that intermittent NPWT has potential to increase the rate of granulation tissue formation compared with adjustable intermittent (AI) NPWT.

• However, interim results from our study showed trends towards greater reductions in wound volume and area, and increases in healthy tissue with AI versus continuous therapy,2 as well as demonstrating functionality and ease of use of a new portable NPWT system.

• We present full results from the study comparing the effects of AI and continuous therapy in the management of acute, sub-acute and chronic wounds administered using the portable NPWT system* (NCT02565043)

Materials and methods

Patients and interventions

• An open, prospective study conducted at nine centres in South Africa (April 2015 to August 2016) in patients with acute, sub-acute and chronic wounds that would benefit from NPWT to achieve adequate wound bed preparation

• Patients were assigned to receive AI or continuous therapy for 28 days; all settings were determined according to patient need and choice of wound dressing kit and filler were at the investigator’s discretion

• Wounds were assessed and imaged, and device functionality and vacuum were assessed at each dressing change (every 48 hours for gauze and every 48–72 hours for foam); adverse events were also assessed

Primary endpoint

• Time to reach readiness for closure by surgical intervention or left for closure by secondary intention

• Defined as >80% healthy granulation tissue; <5% necrotic tissue, reduction in wound area and/or depth from day 0, absence of oedema and infection

Secondary endpoints

• Included wounds ready for closure either by surgical intervention or by secondary intention within 28 days, progress towards wound closure, incidence of infection and pain scores

Statistical analysis

• Assuming a 15% drop-out rate, 80 patients were required to achieve a sample size of 68 patients

• Time to achieve readiness for closure was analysed using Kaplan-Meier estimates, with a Wilcoxon signed rank test applied to reductions in wound dimension and appearance

References


*RENASYS™ TOUCH system (Smith & Nephew)
Results

- A total of 81 patients were assigned to treatment; one patient was excluded from safety and efficacy analysis and 9 more were excluded from efficacy analysis only.

- Patient demographics were similar in both groups except for an increased incidence of anaemia in the continuous therapy group (13.9% vs 2.9%).

- Mean age was 61.3 and 58.6 years and mean BMI was 30.2 and 31.7 kg/m² in the AI and continuous therapy groups, respectively.

- Overall, 74.6% of patients were treated as outpatients; wound characteristics at baseline are presented in Table 1.

- Most wounds were located on the foot, ankle or lower leg in both the AI and continuous therapy groups (71.4% vs 63.9%, respectively).

- Exudate was reported for 37 patients (light [n=21]; moderate [n=13]; heavy [n=3]).

Table 1. Wound characteristics at baseline

<table>
<thead>
<tr>
<th>Wound characteristics</th>
<th>Adjustable intermittent therapy (n=35)</th>
<th>Continuous therapy (n=36)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chronic (pressure, diabetic foot and venous leg ulcers)</td>
<td>10 (28.6%)</td>
<td>14 (38.9%)</td>
</tr>
<tr>
<td>Sub-acute (includes dehisced surgical wounds)</td>
<td>22 (62.9%)</td>
<td>15 (41.7%)</td>
</tr>
<tr>
<td>Acute (surgical and traumatic)</td>
<td>3 (8.6%)</td>
<td>7 (19.4%)</td>
</tr>
<tr>
<td>Area, mean ± SD (cm²)</td>
<td>23.1 ± 23.4</td>
<td>15.4 ± 17.3</td>
</tr>
<tr>
<td>Depth, mean ± SD (mm)</td>
<td>12.0 ± 11.2</td>
<td>11.8 ± 12.0</td>
</tr>
<tr>
<td>Volume, mean ± SD (cm³)</td>
<td>29.9 ± 41.5</td>
<td>24.8 ± 49.4</td>
</tr>
<tr>
<td>Duration, mean ± SD (weeks)</td>
<td>26.8 ± 59.3</td>
<td>48.1 ± 206.8</td>
</tr>
</tbody>
</table>

Table 2. Wound characteristics at end of study

<table>
<thead>
<tr>
<th>Study end point</th>
<th>Adjustable intermittent therapy (n=35)</th>
<th>Continuous therapy (n=36)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Achieved readiness for closure</td>
<td>15 (42.9%)</td>
<td>16 (44.4%)</td>
</tr>
<tr>
<td>Acute</td>
<td>0</td>
<td>4 (25.0%)</td>
</tr>
<tr>
<td>Sub-acute</td>
<td>14 (93.3%)</td>
<td>10 (62.5%)</td>
</tr>
<tr>
<td>Chronic</td>
<td>1 (6.7%)</td>
<td>2 (12.5%)</td>
</tr>
</tbody>
</table>

Primary endpoint

- Median time to achieve the primary endpoint could not be calculated because less than 50% of patients achieved readiness for closure (n=31; 43.7%; Table 2).

  - The lower 95% confidence interval for the primary endpoint was 27 days.
A randomised controlled trial to compare the clinical efficacy and acceptability of adjustable intermittent and continuous Negative Pressure Wound Therapy (NPWT) in a new portable NPWT system*

Martin Forlee,1 Louis van Zyl,2 Hein Louw,3 Jeanne Nel,4 Nyda Fourie,5 Robert Hartley6

Results (cont)

Secondary endpoints

- Estimated median reduction from baseline in wound area (7.3 cm²) and volume (11.7 cm³) were both statistically significant (p<0.001; Figure 1), as was increase in median amount of healthy viable tissue (20.0%; p<0.001)

- By study end the amount of exudate had reduced significantly (p<0.001)

- Eight patients (11.3%) had signs of clinical infection at baseline that resolved during the study

- Nine patients (12.7%) developed signs of infection during the study, five of which resolved by study end

- No pain was reported at 65.3% of dressing applications for AI therapy and 90.6% for continuous therapy. At dressing removal no pain was reported at 62.7% of assessments for AI therapy and 83.3% for continuous therapy

- Both therapy modes were comfortable to wear at more than 99% of dressing changes (99.3% and 99.1% of dressing changes for AI and continuous therapy, respectively)

* RENASYS TOUCH system (Smith & Nephew)

Figure 1. Mean reductions from baseline in wound area and volume (p<0.001 for both)
A randomised controlled trial to compare the clinical efficacy and acceptability of adjustable intermittent and continuous Negative Pressure Wound Therapy (NPWT) in a new portable NPWT system*

Martin Forlee,1 Louis van Zyl,2 Hein Louw,3 Jeanne Nel,4 Nyda Fourie,5 Robert Hartley6

Results (cont)

Secondary endpoints (cont)
• Use of negative pressure settings is shown in Figure 2; the most frequently selected cycle time was '10 min on' and '2 min off'

---

Figure 2. Pressure settings used for AI and continuous therapy during the study

*RENASYS™ TOUCH system (Smith & Nephew)
A randomised controlled trial to compare the clinical efficacy and acceptability of adjustable intermittent and continuous Negative Pressure Wound Therapy (NPWT) in a new portable NPWT system*

Martin Forlee,1 Louis van Zyl,2 Hein Louw,3 Jeanne Nel,4 Nyda Fourie,5 Robert Hartley6


Conclusions

- The device* was effective at managing all types of wound using both therapeutic modes as shown by a statistically significant decrease in estimated wound area and volume. Statistically significant improvements in the amount of healthy viable tissue and exudate levels were also achieved with both AI and continuous therapy.

- Although the primary study endpoint could not be calculated, a mean reduction in wound area of 54.8% was achieved over the 4-week study period.

- Most wounds were on a healing trajectory at study end; therefore, a longer follow-up period may have revealed difference between the two groups.

Acknowledgements

This study was funded by Smith & Nephew and approved by authors.

For detailed product information, including indications for use, contraindications, precautions and warnings, please consult the product’s applicable Instructions for Use (IFU) prior to use.

*RENASYS™ TOUCH system (Smith & Nephew)